



## Research Ethics

### What are research ethics?

Research ethics are a set of principles addressing how researchers and research organisations should conduct themselves when dealing with research participants, their data or tissue, other researchers and colleagues, the users of their research and society in general. The principles apply whether at every stage throughout the career of a researcher from undergraduate student onward.

The process of ethical review is not intended to impede research activity, but to support the researcher in considering the ethical issues and how to manage them, the process also addresses any potential risks to both the researcher and any participants.

### Why are research ethics important?

It is important to conduct research in line with ethical standards for a number of reasons:

- Ethics is an essential element of good research governance
- It helps to support detailed research design and project planning – leading to better experiments and questionnaires
- It is not restricted to medical trials - all types of research must consider ethical issues
- It is vital to consider the ethical consequences of research to avoid bad practice, harm or stress, loss of data, etc.
- Some research may require high level approval in order to be covered by MaCTRI's insurance: Human tissue, Human embryos, Genetically modified organisms, Animal experimentation, Research Council applications, participants under the age of 16 or pregnant women
- Failure to gain the appropriate approval could be viewed as research misconduct and may have serious repercussions.
- Ethical review may be a legal requirement, if your project involves any of the following you should refer to the legislation section below
  - Adults lacking the capacity to provide consent



- NHS patients (or their close relatives), staff, facilities, premises, data or tissue
- Medical devices (this includes creams/ointments, bandages and prosthetics etc.)
- Genetically modified materials
- Drugs or medicines (licensed or unlicensed)

When ethics are considered, this should ensure that the work is acceptable to the research community and other users of the research results.

### See [Participant Information Sheet \(PIS\)](#)

In order to ensure that participants know what they are consenting to, they must be given a Participant Information Sheet to inform them of the research they are being invited to participate in.

## Consent

### Why do we need consent?

Potential recruits to your research must be given sufficient information to allow them to decide whether or not they want to take part.

Where research involves face-to-face interviews, focus groups, direct observation or similar methods of data collection (incl. audio or visual data), participants should normally be given a Participant Information Sheet and asked to sign a consent form.

### Consent Form

Clear evidence must be obtained that the participant has given informed consent to take part in the study. The Institute expects that this will normally be in the form of a signed consent form although other evidence may be acceptable (for example by audio recording consent). If you are considering an alternative way of obtaining consent, you should seek advice from the Institute's Data Protection Officer



Where participants are asked to complete and return a questionnaire, the questionnaire should be accompanied by a covering letter but no consent form is needed: consent is implied by returning the questionnaire. The covering letter, however, should include information similar to that in a Participant Information Sheet.

### **When is consent unnecessary?**

- When using anonymised secondary data.
- Retrospective medical chart studies
- When using published literature
- When consent is implied (for example by the returning of a questionnaire)

There are very few situations, if your research involves people where consent is not required.

**See [Consent Form](#)**

**See [Application for Ethical Approval](#)**

To ensure the safety of the research, ethical approval must be sought from the Institute's Advisory Board. The application for ethical approval form will provide a check list of all the accompanying documents required, including the Research Protocol form.

**See [Research Protocol Template](#)**